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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,306	03/23/2001	Wen Y. Chen	035879/0120	4654

22428 7590 08/08/2006

FOLEY AND LARDNER LLP  
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3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER
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YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/815,306

Applicant(s)

CHEN ET AL.

Examiner

Christopher H. Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,22,28,29,34,35,37-39,45-47,51-54,61-64,66-68,70 and 71 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,4-6,22,28,29,34-39,45-47 and 61-69 is/are allowed.
- 6) ☒ Claim(s) 51-54,70 and 71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

**Re: Chen et al**

1. The amendment filed 5/25/2006 is acknowledged and entered into the record. Accordingly, claims 2-3,7-21,23-27,,30-33,36,40-44,48-50,55-60,65, and 69 are canceled without prejudice or disclaimer.
2. Claims 1,4-6,22,28-29,34-35,37-39,45-47,51-54,61-64,66-68, and 70-71 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections Maintained - 35 USC § 112, 1<sup>st</sup> paragraph***

4. The rejection of claims 51-54 and 70-71 under 35 USC § 112, 1<sup>st</sup> paragraph is maintained for the reasons of record. Applicant argues that the claims have been amended to indicate specific forms of cancer which can be treated by the claimed human growth hormone (hGH) fusion protein. However, the specification as filed fails to show that the receptor antagonist fusion protein comprising a receptor antagonizing domain from hGH with modifications at position 120 and a cytokine (i.e. IL-2, IL-12, or IFN- $\gamma$ ) would be effective in treating breast and breast cancers as claimed. The specification has only provided exemplifications of human prolactin antagonist (hPRLA) fusion proteins and fails to show that hGH antagonists would function in a manner similar to that of hPRLA. As indicated in the previous office action, the art with regard to treating cancer is at most unpredictable and would at the very least require a working

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example showing that some result was obtained when a compound is administered for treatment. In the instant case, there is no extrapolation between the effect of hPRLA and hGH fusion proteins that would lead one of skill in the art to correlate the results of hPRLA to those of hGH antagonists. As such, those of skill in the art would be left to experiment to determine if the results provided in the instant specification would apply to hGH antagonist fusion proteins.

Therefore, applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. As a result, the rejection of claims under 35 USC 112, 1<sup>st</sup> paragraph as lacking enablement is maintained for the reasons of record.

**All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 5/25/2006.**

### ***Conclusion***

Claims 1,4-6,22,28-29,34-35,37-39,45-47,61-64, and 66-68 are allowed.

Claims 51-54 and 70-71 are not allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher Yaen  
Art Unit 1643  
August 3, 2006

  
CHRISTOPHER H. YAEN  
PRIMARY EXAMINER